UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS** **Subcategory Case No. 06-11337**
THIS DOCUMENT RELATES TO: *State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc. et al.*, Civil Action No. 03-11226-PBS	**Hon. Patti B. Saris**

DEFENDANTS DEY, L.P. AND DEY, INC.'S INDIVIDUAL LOCAL RULE 56.1 STATEMENT IN OPPOSITION TO PLAINTIFFS' LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS AS TO THE DEY DEFENDANTS

Pursuant to Local Rule 56.1, Defendants Dey, L.P. and Dey, Inc. (collectively, "Dey") submit the following Rule 56.1 Statement in opposition to Plaintiffs' Local Rule 56.1 Statement of Undisputed Material Facts as to Defendants Dey, L.P. and Dey, Inc. ("CA-Dey-SOF").

I. GENERAL RESPONSES AND OBJECTIONS

Dey generally objects to the CA-Dey-SOF on the grounds that the unnumbered headings misstate, misconstrue and/or mischaracterize the underlying alleged "undisputed" facts they purport to introduce. Dey further objects to the CA-Dey-SOF in that these unnumbered headings lack adequate foundation. *See* Fed. R. Evid. 602. Accordingly, Dey omits these improper and argumentative headings in its Specific Responses to the CA-Dey-SOF below. In addition, Dey generally objects to the CA-Dey-SOF insofar as it inappropriately conjoins completely unrelated or marginally related statements together as one purported factual statement. Dey generally objects to the CA-Dey-SOF insofar as it does not specifically relate to

the Dey drugs at issue on this motion. Dey generally objects to the CA-Dey-SOF insofar as it is immaterial to the issues before the Court on the present motion. Dey generally objects to the citation of evidence which does not support a particular fact or is not the best evidence of a particular fact. Dey's agreement that a fact is undisputed is not an agreement that Plaintiffs' citations support such fact. Dey states that, for the purposes of this motion, the term Subject Drugs shall be defined to include only those NDCs listed in Dey-SOF¶ 6. [1]

II. SPECIFIC RESPONSES TO PLAINTIFFS' STATEMENT OF ALLEGED FACTS

1. During the period from 1994 through 2004, pharmacies and other Medi-Cal providers routinely submitted pharmaceutical claims to Medi-Cal (through its fiscal intermediary, EDS) for reimbursement of the Dey drugs at issue in this action (the "Subject Drugs") that those providers had dispensed to program beneficiaries. (Declaration of Nicholas N. Paul Decl., in Support of Motion for Partial Summary Judgment as to Dey (hereinafter, "Paul"), Ex. 1 (Gorospe Decl.), at ¶¶ 3, 4.)

RESPONSE:

Dey does not dispute that providers submitted pharmaceutical claims to Medi-Cal for reimbursement of drugs those providers had dispensed to program beneficiaries. Dey further states that the reimbursement claims contained the providers usual and customary charge to the general public. (Reid Opp. Decl. Ex. 1, at 689:5-692:10).[2] Dey however disputes CA-Dey-SOF ¶ 1 on the grounds that the declaration of J. Kevin Gorospe refers generally to all defendants in this action and all the "Subject Drugs" and does not refer specifically to Dey or Dey's drugs. Dey further objects to CA-Dey-SOF ¶ 1 to the extent that the term "Subject Drugs" as used by

[1] "Dey-SOF" refers to Dey's Statement of Undisputed Material Facts in Support of Dey, Inc. and Dey, L.P.'s Motion for Partial Summary Judgment, Dkt. No. 6695.

[2] "Reid Opp. Decl., Ex. __" refers to the Declaration of Sarah L. Reid in Support of Defendants Dey, L.P. and Dey, Inc.'s Opposition to Plaintiffs' Motion for Partial Summary Judgment and the exhibits annexed thereto.

Plaintiffs includes NDCs not listed in Dey-SOF ¶ 6 on the grounds that there is no evidence in the record concerning those NDCs and thus they are not properly part of this case.

2. Medi-Cal paid those claims (through EDS) with Government funds. (Paul Ex. 1 (Gorospe Decl.), at ¶¶ 3, 4.)

RESPONSE:

Dey disputes CA-Dey-SOF ¶ 2 on the grounds that the term "Government funds" is vague, ambiguous, and undefined. Dey further states that, throughout the relevant time period, at least 50% of each claim at issue was paid with funds provided by the federal government. *See* 42 U.S.C.A. § 1396d(b) (2009). Dey further states that the amounts paid for the Subject Drugs have been further offset by rebate payments made by Dey to the state of California pursuant to federal law. *See* 42 U.S.C. § 1396r-8.

3. Pursuant to applicable statutory and regulatory requirements, the claims were adjudicated and paid *at the lesser of* the provider's usual and customary charge or at the Cost of the Drug Product plus a dispensing fee. By statute, the total payment was then reduced by an amount varying over time from $.10 to $.50 per claim. (Paul Ex. 1 (Gorospe Decl.), at ¶¶ 5a, 5b, 6.)

RESPONSE:

Dey disputes CA-Dey-SOF ¶ 3 on the grounds that the term "Cost of the Drug Product" is vague, ambiguous, and undefined. Dey further disputes CA-Dey-SOF ¶ 3 on the grounds that California was never limited by law to paying the cost of a drug on a drug-by-drug basis. Rather, for drugs subject to a Federal Upper Limit ("FUL"), federal regulations merely limited payment in the aggregate, across all drugs, to the amount that would result from the application of the FUL plus a reasonable dispensing fee. (Robben Decl., Ex. 6.)[3] For all "other drugs" not subject to a FUL, a state agency's payment "must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the (1) Estimated Acquisition Cost ("EAC")

[3] "Robben Decl., Ex. __" refers to the Declaration of Philip D. Robben in Support of Defendants' Motions for Partial Summary Judgment and the exhibits annexed thereto, Dkt. Nos. 6702 to 6702-69.

plus reasonable dispensing fees established by the agency or (2) providers' usual and customary charges to the general public." *See* 42 C.F.R. § 447.332(b) (2004). In comments adopting these regulations, HCFA explicitly noted payments for some drugs could exceed limits, provided that the limits were met in the aggregate:

> 1. Increased State Flexibility
>
> * * *
>
> Under these final regulations, State agencies will be able to make higher payments for some listed drugs as long as they pay at rates lower than those listed for other drugs on the list. … Similarly, State agencies may employ essentially the same approach in meeting the limits for all other drugs. That is, the same principal of balancing payment increases for some drugs with decreases for other drugs also applies in determining whether aggregate payments exceed the limit.

Fed. Reg. Vol. 52, No. 147, July 31, 1987, at p. 28655.

Within these guidelines, California had broad discretion to set its reimbursement methodology as it saw fit (Robben Decl., Ex. 2, at 431:4-9; Robben Decl., Ex. 3, at HHC002-0565; Robben Decl., Ex. 4, at 433:8-449:12; Robben Decl., Ex. 5, at 209:11-210:15), subject only to the requirement that its payments were consistent with efficiency, economy, and access to quality care (*see* Joint SOF at ¶¶ 14, 52, 56, 57[4]; *see also* Robben Decl., Ex. 7, at 108:3-109:13; Robben Decl., Ex. 8, at 307:13-308:5; Robben Decl., Ex. 9, at 464:2-465:7; Robben Decl., Ex. 10, at 49:10-51:18). Dey further refers the Court to statutes and regulations governing California's reimbursement methodologies as the best evidence of Medi-Cal's reimbursement methodology during the relevant time period.

4. The Cost of the Drug Product was set at *the lowest of* the drug's Estimated Acquisition Cost ("EAC"), the Federal Allowable Cost (FAC, a/k/a FUL), or the

[4] "Joint SOF at ¶ __" refers to the Defendants' Joint Statement of Undisputed Material Facts in Support of Their Motions for Partial Summary Judgment, Dkt. No. 6703.

Maximum Allowable Ingredient Cost (MAIC).[5] (Paul Ex. 1 (Gorospe Decl.), at ¶ 5a, 5b.)

RESPONSE:

Dey disputes CA-Dey-SOF ¶ 4 on the grounds that the term "Cost of the Drug Product" is vague, ambiguous, and undefined. Dey does not dispute that, throughout the relevant time period, Medi-Cal reimbursed pharmacists and other Medicaid providers who dispensed the Subject Drugs at the lower of EAC, the FUL, the Maximum Allowable Ingredient Cost ("MAIC"), or the charge submitted by the provider. (Joint SOF at ¶ 18; Robben Decl., Ex. 13.) Dey further refers the Court to statutes and regulations governing California's reimbursement methodology as the best evidence of Medi-Cal's reimbursement methodologies during the relevant time period.

Dey disputes CA-Dey-SOF ¶ 4 on the grounds that California never intended payments based on EAC, FUL, or MAIC to approximate providers' actual cost for the drug product on a drug-by-drug basis. Dey adopts herein its response to CA-Dey-SOF ¶ 3 and further states that, consistent with the flexibility afforded by the federal regulations, California adopted reimbursement methodologies that it knew would pay providers more than their actual acquisition costs, particularly for generic drugs, for its own policy reasons. For instance, when it adopted the 1987 federal FUL regulations, California noted with approval that it would pay a "spread" of more than 100 percent for a generic drug and considered this a benefit for the Medi-Cal program, because it would promote the use of lower-cost generics. (Joint SOF at ¶ 26; Robben Decl., Ex. 17.) During the late 1990s and early 2000s, California considered multiple proposals to reduce its reimbursement payments to levels that would be closer to what providers paid to acquire drugs, but never adopted these proposals, citing concerns that the reduced

[5] There are no claims paid at MAIC at issue in this case.

payments would limit Medi-Cal beneficiaries' access to care. (Joint SOF at ¶¶ 33, 35, 36; Robben Decl., Exs. 24, 25, 27-29.) When California did revise its reimbursement methodology, first in 2002 and again in 2004, it made only modest reductions to reimbursement payments and acknowledged that its payments for generic drugs still significantly exceeded providers' acquisition costs. (Joint SOF at ¶¶ 51-59; Robben Decl., Exs. 35-39.)

5. The Estimated Acquisition Cost for the Subject Drugs was determined at all relevant times at the AWPs reported by First Data Bank ("FDB") less a discount of either 5% (from 1994 through October 2002), 10% (from November 2002 through August 2004), or 17% (August 2004 through December 2004). (Paul Ex. 1 (Gorospe Decl.), at ¶¶ 5b, 7.)

RESPONSE:

Dey does not dispute that California used these formulas to calculate EAC for some reimbursement purposes but states that the underlying statutes and regulations are the best evidence of California's reimbursement methodologies. Dey further states that California's claims data is the best evidence of what criteria was actually used to determine reimbursement for claims paid based on EAC. Dey further states that EAC would be used to calculate reimbursement only when the resulting payment would be lower than the usual and customary charge submitted by the provider. (Reid Opp. Decl. Ex. 1, at 689:5-692:10).

6. Throughout the relevant time period, Dey set AWPs for its products. (Paul Ex. 2 (11/1/01 Robert Mozak Dep.), at 23:23- 24:1.)

RESPONSE:

Dey does not dispute that it set AWPs for its products at launch. In fact, the testimony cited by Plaintiffs specifically discusses Dey's policy to report AWP to government agencies at any new product launch. (Paul Decl., Ex. 2 at 23:2-24:4).[6] Dey further states that it reported an

[6] "Paul Decl., Ex. __" refers to the Declaration of Nicholas N. Paul in Support of Plaintiffs' Motion for Partial Summary Judgment as to Defendants Dey, L.P. and Dey, Inc. and the exhibits annexed thereto, Dkt. Nos. 6692 to 6692-25.

AWP for the Subject Drugs to the publishers so that the Subject Drugs could be recognized by the industry and third party payors as generics. (Paul Decl., Ex. 4, at 731:12-24; Paul Decl., Ex. 3, No. 11 at 13-14.) Dey further states that while it reported both its AWP and WAC prices to the drug pricing compendia, what happened to those prices after they were received by the compendia was in the control of the compendia, and not Dey. (Reid Opp. Decl., Ex. 2, at 135:1-136:10). A review of the prices published by the various compendia show that the prices were updated at various times, and not all of the compendia list the same price at the same time. (Reid Opp. Decl., Ex. 3, at 2).

7. During the relevant time period, Dey set AWPs for its generic drugs before they were first sold and generally did not subsequently change the initially-set AWPs. Dey's Responses to California's First Set of Requests for Admission, June 30, 2009:

> Request No. 11: "Admit that Dey's AWPs for each of the Subject Drugs was not based on an average of any wholesale prices."
>
> Dey's Response: "…Dey states that, during the relevant time period, Dey's practice has been to set AWPs for its generic drugs before they are first sold and not to subsequently change that AWP.

(Paul Decl., Ex. 3 (Dey's Resp. to First Set of Req. for Admis.), No. 11 at p. 13.)

RESPONSE:

Dey does not dispute that it set AWPs for its generic drugs at launch, before any products were sold, and that it would generally not subsequently change them, but states that this practice was in accordance with industry practice. Ms. Marrs, Dey's former Chief Financial Officer, testified:

> Q. And has it historically been typically the case that Dey does not change the AWP once it's been set at the time of launch of a new product?
>
> A. For generic products, that's correct. It's again, my understanding that that's an industry practice, that AWP is not changed.

(Reid Opp. Decl., Ex. 2, at 132:5-12; *see also* Reid Opp. Decl., Ex. 4, at 502:1-503:8; Reid Opp. Decl., Ex. 5, at 736:21-737:20; Paul Decl., Ex. 7 at ¶ 16).

Dey further states that it regularly updated its WAC in a manner that directly reflected underlying pricing activity. (Reid Opp. Decl., Ex. 6, at 372:11-20). Ms. Marrs explained that as market prices decline, Dey reduced its reported WAC. (Reid Opp. Decl., Ex. 2, at 136:16-21). Moreover, Dey notified price reporting services and state Medicaid offices as soon as the WAC was lowered. (Reid Opp. Decl., Ex. 2, at 137:6-17).

Moreover, pursuant to the terms of Dey's rebate agreement with the Department of Health and Human Services, to which the State of California is a party, Dey has calculated and reported, on a quarterly basis, its net prices to wholesalers and distributors that take into account discounts, rebates, chargebacks and any other price adjustments, in the form of AMPs. (Reid Opp. Decl., Ex. 7, at § I(a); Reid Opp. Decl., Ex. 2, at 168:10-15). AMP is defined under the rebate agreement as "the average unit price paid to the Manufacturer for the drug in the States by *wholesalers* for drugs distributed to the retail pharmacy class of trade" and "includes cash discounts allowed and all other price reductions … which reduce the actual price paid." (Reid Opp. Decl., Ex. 7, at § I(a) (emphasis added).) CMS used the AMPs reported by Dey to calculate URAs, which it in turn reported to the states, including California. (Reid Opp. Decl., Ex. 7, at 5). For multiple-source non-innovator drugs, the URA is 11% of the AMP. *See* 42 U.S.C. 1396r-8(c)(3)(A – B); Reid Opp. Decl., Ex. 7, at 3. California invoices Dey for rebates based on the URAs it receives from CMS. *See* Reid Opp. Decl., Ex. 7, at 5; 42 U.S.C. 1396r-8(b)(2).

Dey further states that California has selectively quoted from Dey's Objections and Responses to the State of California's First Set of Requests for Admission. The relevant paragraph from Dey's Objections and Response to Request No. 11 states in full that:

> Subject to and without waiving the foregoing general and specific objections, Dey states that, during the relevant time period, Dey's practice has been to set AWPs for its generic drugs before they are first sold and not to subsequently change that AWP. Dey understands that this is consistent with industry practice. There are some instances to the contrary depending on the market and/or other forces. Dey's AWPs for its brand name drugs at issue in this action have been set and revised as Dey's WACs have changed. Dey understands that this practice is also consistent with industry practice.

(Paul Decl., Ex. 3, No. 11 at 13).

8. When Dey was the first to market a generic product, Dey set the AWP at approximately 10 percent below the branded product. (Paul Ex. 4 (3/13/03 Robert Mozak Dep.), at 731:11-732:9; Paul Ex. 5 (3/24/03 Charles A. Rice Dep.), at 604:16-21; Paul Ex. 3 (Dey's Resp. to First Set of Req. for Admis.), No. 11 at pp. 13-14.)

RESPONSE:

Dey does not dispute that, at launch, pricing for a first-to-market generic is set in relationship to the brand AWP. (Reid Opp. Decl., Ex. 2, at 129:22-130:11). First DataBank advised Dey to set the AWP at approximately 10 percent below the branded product. (Paul Decl., Ex. 4, at 731:12-24; Paul Decl., Ex. 3, No. 11 at 13-14 ("Early on in Dey's business, Ed Edelstein of First Data Bank advised Dey that, for purposes of acceptance by the reporting services of Dey's product as a generic, the AWP for that product should be a minimum of 10% below the innovator product's AWP, and historically, Dey has observed this principle.").)

Dey's practice of establishing AWPs for the Subject Drugs at a percentage lower than the therapeutically equivalent brand AWPs was consistent with industry practice. (Reid Opp. Decl., Ex. 4, at 460:2-462:10). According to Patricia Kay Morgan, former Manager of Editorial

Services at First DataBank, there was a "perception in the industry" that a generic drug had to be priced at least 10 percent less than the brand price. (Reid Opp. Decl., Ex. 8, at 21:4-18).

9. When Dey launched a product and there was already a competitive generic product on the market, Dey set its AWP by reference to the competitor's AWP. (Paul Ex. 4 (3/13/03 Robert Mozak Dep.), at 731:11-732:9.)

RESPONSE:

Dey does not dispute that Mr. Mozak testified that when it was not the first generic on the market, Dey would "look at the competitive generic," and "usually matched their AWP or – and – and/or WAC. It would have been at basically what the competition was doing." (Paul Decl., Ex. 4, at 732:2-9.)

10. Dey knew that "competition forces prices down on [a] generic product." (Paul Ex. 4 (3/13/03 Robert Mozak Dep.), at 739:7-16. Dey responded to such competition by consistently lowering the selling price of its products. (Paul Ex. 6 (4/30/02 Robert Mozak Dep.), at 272:9-20.)

RESPONSE:

Dey does not dispute that the generic drug market is characterized by intense competition and that as competition increases, the contract prices and profit margins for generic drugs decline.

11. Dey generally did not change its reported AWPs in response to changes in transaction prices for its products; its practice was to set a product's AWP at launch and to not change that AWP. (Paul Ex. 7 (Decl. of Russell Johnston in Support of Plaintiff's Ex Parte Application for a Temporary Restraining Order, *Dey v. First DataBank*, Superior Court of California, County of Napa, Case No. 26-21019, filed April 15, 2003), at 4, ¶16; Paul Ex. 8 (11/7/02 Charles A. Rice Dep.), at 427:3-4; *see also* Number 7 above.)

RESPONSE:

Dey does not dispute that it set AWPs for its generic drugs at launch and that those AWPs generally remained constant, but states that this practice was in accordance with industry practice. Ms. Marrs testified:

> Q. And has it historically been typically the case that Dey does not change the AWP once it's been set at the time of launch of a new product?
>
> A. For generic products, that's correct. It's again, my understanding that that's an industry practice, that AWP is not changed.

(Reid Opp. Decl., Ex. 2, at 132:5-12; *see also* Reid Opp. Decl., Ex. 4, at 502:1-503:8; Reid Opp. Decl., Ex. 5, at 736:21-737:20; Paul Decl., Ex. 7 at ¶ 16).

Dey disputes CA-Dey-SOF ¶ 11 on the grounds that it mischaracterizes the declaration of Russell Johnston. Mr. Johnston does not refer to Dey specifically nor does he discuss Dey's price-reporting practices, but rather speaks to industry practice generally:

> It is common within the industry that the reported AWP for a generic drug, once set, will tend to remain constant and not change during the life of the product (with the exception of inadvertent errors on the part of First DataBank). Discounts applied to AWP by third party payors, however, often change over time due to changing market conditions. This has been the case through the years that I have worked in the pharmaceutical industry.

(Paul Decl., Ex. 7 at ¶ 16.) Dey hereby incorporates its response to CA-Dey-SOF ¶ 7.

Dey further states that, since 1999, it sent letters to state Medicaid administrators, including Medi-Cal administrators, in which Dey explicitly described the nature of its published AWPs and WACs when new products were introduced or when prices were changed. (Reid Decl., Ex. 28; Reid Decl., Ex. 29; Reid Decl., Ex. 30; Reid Decl., Ex. 31; Reid Decl., Ex. 32; Reid Decl., Ex. 33; Reid Decl., Ex. 34; Reid Decl., Ex. 35; Reid Decl., Ex. 36; Reid Decl., Ex. 37; Reid Decl., Ex. 38; Reid Decl., Ex. 39.)[7] For example, in one such letter dated August 10, 1999, Robert Mozak, Dey's Executive Vice President for Sales and Marketing, wrote to state Medicaid administrators as well as regional Medicare benefits administrators, apprising them of a new NDC number for Dey's Albuterol Sulfate Inhalation Solution 0.5%. (Reid Decl., Ex. 30.)

[7] "Reid Decl., Ex. __" refers to the Declaration of Sarah L. Reid in Support of Dey, L.P. and Dey, Inc.'s Motion for Partial Summary Judgment and the exhibits annexed thereto, Dkt. Nos. 6699 to 6699-46.

The letter describes Dey's WAC as follows:

> As you know, WAC is referred to by data reporting services and government agencies as an "estimate," and Dey believes that WAC generally means the invoice price charged by a pharmaceutical manufacturer to drug wholesalers. As you also know, WAC does not include the net effect of discounts from invoice price (based on volume of purchases, speed of payment and other factors), rebates, chargebacks, administration fees and other such cost adjustments which are well-known and commonplace in the pharmaceutical industry and can affect, to a greater or lesser degree, the actual "final" cost to each purchaser. These discounts may not be determined until some months after the date of invoice. Therefore, we remind you that WAC may well not be representative of actual market costs to those entities which you are reimbursing under Medicaid.

(Reid Decl., Ex. 30 (emphasis in original).)

The letter goes on to describe AWP as follows:

> Further, as you also know, the Average Wholesale Price (or "AWP") per unit listed above does not represent actual wholesale prices which will be charged or paid for this product. It is Dey's practice to set an AWP before a product is first sold and not subsequently to change that figure. We understand that this is consistent with industry practice and is understood by state and federal Medicaid regulators.

(Reid Decl., Ex. 30 (emphasis in original).) The letter closes with the following sentence: "If you need additional information, please feel free to contact Todd Galles, Senior Product Manager, at 800-755-5560, ext. 7450." (Reid Decl., Ex. 30.)

Len Terra, Chief of the Medi-Cal Drug Program, was one of the recipients of this letter. (Reid Decl., Ex. 30, at DEY-LABS-0415394.) Todd Galles, the Dey contact person listed on the August 1999 letter discussed above, testified that he had never been contacted by anyone regarding the letter. (Reid Decl., Ex. 40, at 410:1-411:15.) In addition to the general letters, many letters were specifically addressed to Medi-Cal officials, including: (i) a March 16, 1999 letter to Kevin Gorospe, Senior Pharmacy Consultant for Medi-Cal Benefits Branch, introducing

the EasiVent Mask; (ii) July 18, 2000 letter to Len Terra, Chief of the Medi-Cal Drug Program, introducing a new Albuterol Inhalation Aerosol, 17g Metered Dose Inhaler Kit and Refill; (iii) August 2, 2000 letter to Len Terra, Chief of the Medi-Cal Drug Program, introducing the private label Astech Peak Flow Meter; and (iv) January 2, 2001 letter to Len Terra, Chief of the Medi-Cal Drug Program, regarding price changes for certain Dey drugs. (Reid Decl., Ex. 29, at DEY-MDL-0105075; Reid Decl., Ex. 32, at DEY-MDL-0105085, 090; Reid Decl., Ex. 34, DEY-LABS-0415539; Reid Decl., Ex. 35, at DEY-BO0018910, 912.)

Kevin Gorospe testified that he recalled receiving letters with disclosures like the ones in Dey's price notification letters from manufacturers. Mr. Gorospe could not recall any attempt to contact any manufacturer, and certainly not Dey, in response to such disclosures. Mr. Gorospe further did not recall such disclosures prompting any investigation:

> Q. Did it ever occur that when you passed on one of those letters to Mr. Terra he -- he asked you to subsequently investigate anything about the company that had sent it?
>
> A. No, not that I can recall.
>
> Q. Do you remember any -- any type of letter like this exhibit touching off some type of investigation, whether you did it or not?
>
> MR. PAUL: Objection to form.
>
> THE WITNESS: No.

(Reid Decl., Ex. 27, at 688:16-689:3).

12. Dey's practice of dropping the price of a generic product while maintaining the originally-reported AWP served to increase the reimbursement spread of that product.

Dey's Responses to California's First Set of Requests for Admission, June 30, 2009,

Request No. 24

> Admit that you never disclosed to Medicaid officials responsible for reimbursement for Your Subject Drugs the actual spreads on those products.
>
> Dey's Response:
>
> ….Second, if the spread for a particular generic Dey drug is getting larger, it is almost always because the AWP of the drug is remaining the same, while the actual selling price is getting lower.…
>
> (Paul Ex. 3 (Dey's Resp. to First Set of Req. for Admis.), No. 24 at p. 32; Paul Ex. 9 (2/7/94 Robert Mozak letter), at DEY-BO-0189566-0189570 (Dey characterizes its pricing on a product as the "lowest net price, highest retailer spread versus AWP").)

RESPONSE:

Dey disputes CA-Dey-SOF ¶ 12. Plaintiffs selectively and disingenuously quote from a 14-page response in Dey's Objections and Responses to the State of California's First Set of Requests for Admission. The paragraph which contains the passage quoted by Plaintiffs does not support the assertion that Dey's practice of leaving its AWPs unchanged despite decreasing contract prices served to increase the "reimbursement spread" of Dey's products. In fact, the paragraph explains that "contrary to Plaintiffs' claims, Dey does not benefit from increased spreads":

> First, drug manufacturers, like Dey, do not receive the money which comes from the spread. The so-called spread in the reimbursement payments goes to the providers. Second, if the spread for a particular generic Dey drug is getting larger, it is almost always because the AWP of the drug is remaining the same, while the actual selling price is getting lower. At the same time Dey's costs are increasing and its margins are declining.

(Paul Decl., Ex. 3, No. 24 at 31-32.)

The so-called "spread" between Medi-Cal's reimbursement payments and providers' actual acquisition costs was not the result of Dey's price reporting practices, but rather the result of California's knowing and deliberate decision to calculate reimbursement payments based on AWP, knowing that the resulting payment would exceed providers' actual acquisition costs.

(*See* Joint SOF at ¶¶ 22-49, 58-59.) Dey regularly updated its published WACs for its drugs as competition in the marketplace pushed the prices for those drugs lower. If California wanted to, it could have reimbursed on Dey's WACs instead. In fact, California considered moving to a reimbursement methodology based partly on WACs, but instead deliberately chose to maintain its AWP-based reimbursement methodology to ensure that reimbursement payments would remain high enough so that Medi-Cal beneficiaries had adequate access to quality medical care. (*See* Joint SOF at ¶¶ 54-59.)

Dey does not dispute that Plaintiffs selectively quote from a letter from Robert Mozak to a wholesaler dated February 7, 1994, a mere month into the relevant time period. However, Dey states that Mr. Mozak merely points out, in one bullet-point within a two-page letter enumerating various selling points, the difference between net prices and AWP. In fact, a full paragraph on the first page of the same letter is devoted to the superior product features of Dey's unit-dose albuterol and metaproterenol. (*See* Paul Decl., Ex. 9.)

13. Dey acknowledged that it did not lower its reported AWPs because, given the reimbursement system, customers would not buy Dey's products if it lowered the AWPs. (Paul Ex. 10 (5/15/08 Rule 30(b)(6) (Pamela Marrs) Dep.), at 133:6-9, 141:14-142:4.)

RESPONSE:

Dey disputes CA-Dey-SOF ¶ 13. Ms. Marrs did not testify that Dey did not lower its reported AWPs because, given the reimbursement system, customers would not buy Dey's products if AWPs were lowered. In fact, Ms. Marrs testified about a specific incident in 2003, described in more detail below, where First DataBank unilaterally lowered Dey's AWP, describing customer reactions and the resultant events.

In order to compete in the generic marketplace, a manufacturer needs a level playing field on which to compete, which is accomplished by having an AWP that is approximately 10 percent

below the brand AWP and in line with generic competitors' AWPs for the same product. (Reid Opp. Decl., Ex. 4, at 469:12-15; Reid Opp. Decl., Ex. 5, at 773:4-21; Reid Opp. Decl., Ex. 9, at 43:18-44:13).

As Dey's experience shows, the failure to follow the industry practice of setting AWP for a generic at 10 percent off the brand forced Dey out of business with respect to its ipratropium nasal spray product. As Ms. Marrs testified:

> We did have a product that we tried to launch and it was in the middle of when people were trying to figure out what all this litigation was about. It was a nasal spray product. We launched. We set a very low WAC and AWP, much lower than our competitors, and we had to discontinue the product. No one would buy it.
>
> So it pretty much put us out of business on that product.

(Reid Opp. Decl., Ex. 4, at 368:11-369:1).

Moreover, in April 2003, Dey almost lost its entire generic business when First DataBank and Medispan unilaterally reduced Dey's AWP without reducing the AWPs of Dey's competitors. (Reid Opp. Decl., Ex. 10, at ¶¶ 7-12; Reid Opp. Decl., Ex. 11, at ¶¶ 3-6; Reid Opp. Decl., Ex. 12, at ¶¶ 3-8). During the week of April 7, 2003, First DataBank and Medispan began to list AWPs for Dey's albuterol, ipratropium, and cromolyn products that bore no relationship to Dey's suggested AWPs or to any AWP previously listed for Dey's products. (Reid Opp. Decl., Ex. 10, at ¶ 7). First DataBank and Medispan did not change the AWPs reported for products of Dey competitors, however. Dey only became aware of this change on April 10, 2003 when it received a series of customer complaints regarding the AWPs published by First DataBank and Medispan. (Reid Opp. Decl., Ex. 10, at ¶¶ 6-7, 14; Reid Opp. Decl., Ex. 12, at ¶¶ 4-6; Reid Opp. Decl., Ex. 11, at ¶¶ 3-6).

The impact of First DataBank and Medi-Span's actions rapidly became apparent. Within one day, numerous customers contacted Dey and stated that, as a result of reduced

reimbursement payments caused by these changes, they would be forced to switch to Dey's competitors. (Reid Opp. Decl., Ex. 10, at ¶¶ 6-7, 14; Reid Opp. Decl., Ex. 12, at ¶¶ 4-6; Reid Opp. Decl., Ex. 11, at ¶¶ 3-6).

Days after the first customer complaints began pouring in, Dey made an application for a temporary restraining order to restore the status quo and to reinstate the AWPs that had been in place prior to the change. Dey's application was granted and the matter was later settled. Had the AWPs not been reinstated, Dey would have been forced to almost immediately curtail its manufacturing operations in Napa in anticipation of a mass customer defection, and most likely would have ceased to be a viable company. (Reid Opp. Decl., Ex. 13, at ¶ 9).

Dey further states that it set its AWPs in a manner that was consistent with industry practice, and that it did not generally change the AWPs for the Subject Drugs because it understood that was consistent with industry practice for generic drugs. (Reid Opp. Decl., Ex. 2, at 132:5-12; *see also* Reid Opp. Decl., Ex. 4, at 502:1-503:8; Reid Opp. Decl., Ex. 5, at 736:21-737:20; Paul Decl., Ex. 7 at ¶ 16). The one time that Dey departed from this practice and set AWPs that were much lower than its competitors' AWPs, no one would buy the products. (Reid Opp. Decl., Ex. 4, at 368:11-369:1).

Dey further states that monitoring state reimbursement methodologies was not an important part of its business and Dey did not track how its products were being reimbursed by various state Medicaid agencies nor did it set prices based on such. (Reid Opp. Decl., Ex. 2, at 185:7-187:8).

14. Dey was aware that it was necessary to report AWPs to the pricing compendia in order for its products to be reimbursed by third party payers, such as Medi-Cal. Paul Ex. 11 (Compl. for Injunctive Relief, *Dey v. First Data Bank*, Superior Court of California, County of Napa, Case No. 26-21019, filed April 15, 2003), at 7:27-28; Paul Ex. 8 (11/7/02 Charles Rice Dep.), at 409:13-25.) The former head of Dey's Sales and Marketing, Robert Mozak, also knew that Medicaid authorities calculated reimbursement based on prices reported to FDB or Medispan or Red Book. (Paul Ex. 12 (11/6/02 Robert Mozak Dep.), at 492:7-13; Paul Ex. 13

(10/30/01 Charles Rice Dep.), at 119:11-120:7; Paul Ex. 10 (5/15/08 Rule 30(b)(6) (Pamela Marrs) Dep.), at 296:6-22.)

RESPONSE:

Dey disputes CA-Dey-SOF ¶ 14 because the testimony cited does not provide evidence of any general pattern or knowledge of Dey which was improper or related to pricing or reporting of AWP to the compendia. The testimony cited by Plaintiffs simply confirms that as part of its business, Dey was aware of state Medicaid reimbursement. However, Dey did not track how its products were being reimbursed by various state Medicaid agencies nor did it set prices based on such. (Reid Opp. Decl., Ex. 2, at 185:7-186:1). Ms. Marrs, explained as follows:

> I mean, the documents that I've seen from the company at this point don't show evidence that there was a monthly report or any regular report that was distributed to people that had this kind of information on it. I'm not saying that people weren't generally aware that that was the reimbursement formula in some way. I -- I haven't seen documents that would suggest it was tracked in a regimented and structured way.

(Reid Opp. Decl., Ex. 2, at 185:13-186:1).

15. From 1992 to April 2003 First DataBank published AWPs for Dey's drugs as reported by Dey. For over ten years the only AWPs listed in First DataBank's databases for Dey's NDCs were those submitted by Dey. (Paul Ex. 11 (Compl. for Injunctive Relief, *Dey v. First Data Bank*, Superior Court of California, County of Napa, Case No. 26-21019, filed April 15, 2003), at 8:22-28; Paul Ex. 14 (7/10/08 Rule 30(b)(6) (Pamela Marrs) Dep.), at 467:19-22.)

RESPONSE:

Dey disputes CA-Dey-SOF ¶ 15 because, while Dey reported AWP prices to the drug pricing compendia, what happened to those prices after they were received by the compendia was in the control of the compendia, and not Dey. A review of the prices published by the various compendia show that the prices were updated at various times, and not all of the compendia list the same price at the same time. (Reid Opp. Decl., Ex. 3, at 2). Moreover, Ms.

Marrs testified that Dey did not control the publication of Dey's prices and that Dey could not know if the published prices accurately reflected those reported by Dey. (Reid Opp. Decl., Ex. 2, at 135:1-136:10).

Indeed, immediately preceding the testimony cited by Plaintiffs, Ms. Marrs reiterated that Dey did not check to see whether the published price matched that reported by Dey:

> Q. You don't know one way or the other, or are you telling me Dey did not check to see that its published AWPs were the ones it reported?
>
> Ms. Giuliana: Objection. Form.
>
> A. I know there was one document I saw that had been transmitted to one of the reporting services. I think it was First DataBank. That had check marks on it that made it look like somebody had checked it off. But then I also know that I followed up with – I don't remember now if it was Russ or Todd. I think it might have been Russ – to find out if they verified information after they submitted it, and he said that they would get a confirmation back that it was received, but they wouldn't physically check to make sure the right number was posted in the reporting service.

(Paul Decl., Ex. 14 at 467:1-17.)

16. Dey maintained a computer database specifically for Medicaid AMP calculations that contained average prices for all Dey's drug products. (Paul Ex. 15 (5/14/08 Rule 30(b)(6) (Gary Walker) Dep.), at 151:10-21.)

RESPONSE:

Dey disputes CA-Dey-SOF ¶ 16 on the grounds that it does not accurately paraphrase Gary Walker's testimony. Mr. Walker testified that Dey maintains a computer system that "contains our AMPs, average prices, but wouldn't have our pricing structure, like the CSP table and contract pricing, things like that." (Paul Decl., Ex. 15 at 151:13-16.) Dey refers to the definitions of AMP contained in 42 U.S.C. § 1396r-8 and the rebate agreement entered into between Dey and the United States Secretary for Health and Human Services on February 28, 1991. Dey disputes any implication that it should have provided its AMPs – which it reported on

a quarterly basis to CMS – to pricing compendia, or that California had any expectation that it would do so.

Dey hereby incorporates its response to CA-Dey-SOF ¶ 11 and evidence cited therein.

Dey hereby incorporates its response to CA-Dey-SOF ¶ 7 and evidence cited therein.

17. Dey calculated the average sales prices for its drug products at least every month. (Paul Ex. 16 (7/9/08 Rule 30(b)(6) (Gary Walker) Dep.), at 376:6-11.)

RESPONSE:

Dey disputes CA-Dey-SOF ¶ 17 to the extent it implies that Dey's behavior is somehow illegal or prohibited. Dey further disputes CA-Dey-SOF ¶ 17 on the grounds that it mischaracterizes the testimony of Gary Walker. Mr. Walker did not testify that Dey "calculated" average sales prices monthly, but that he would generate monthly reports summarizing Dey's average sales prices. Dey further states that Mr. Walker indicated in his testimony that Dey reported average sales prices to CMS. (*See* Reid Opp. Decl., Ex. 14, at 360:9-16). Dey disputes CA-Dey-SOF ¶ 17 as immaterial and irrelevant on the grounds that California never required or expected Dey to report any such prices to pricing compendia. Dey further disputes any implication that it should have provided the "average sales prices" referenced in Mr. Walker's testimony to pricing compendia, or that California had any expectation that it would do so as there is no evidence in the record to support such a conclusion.

Dey hereby incorporates its response to CA-Dey-SOF ¶ 11 and evidence cited therein.

18. Dey generated a monthly Sales Commentary that included monthly net sales by product, monthly average price by product per carton and per unit, and monthly net sales reports after rebates, discounts and administrative fees. (Paul Ex. 8 (11/7/02 Charles A. Rice Dep.), at Ex. 349.) Dey also generated monthly product summary reports that reflected wholesale cost, contract cost and chargeback difference per product. (Paul Ex. 17 (3/29/06 Lewis Mow Dep.), at Ex. 287.)

RESPONSE:

Dey disputes CA-Dey-SOF ¶ 18 to the extent it implies that Dey's behavior is somehow illegal or prohibited. Dey disputes CA-Dey-SOF ¶ 18 as immaterial and irrelevant on the grounds that California never required or expected Dey to report any such information to pricing compendia. Dey further disputes any implication that it should have provided the information referenced in CA-Dey-SOF ¶ 18 to pricing compendia, or that California had any expectation that it would do so as there is no evidence in the record to support such a conclusion.

Dey hereby incorporates its response to CA-Dey-SOF ¶ 11 and evidence cited therein.

Dey hereby incorporates its response to CA-Dey-SOF ¶ 7 and evidence cited therein.

19. Dey sent its AWPs to First DataBank, but did not send the contract prices. (Paul Ex. 18 (1/20/03 Eve Gmeiner Dep.), at 99:12-100:5.)

RESPONSE:

Dey disputes CA-Dey-SOF ¶ 19 on the grounds that it mischaracterizes the testimony of Eve Gmeiner. In the testimony cited by Plaintiffs, Eve Gmeiner did not testify that Dey sent its AWPs to First DataBank, but not its contract prices. Ms. Gmeiner testified that the "broad price categories" that Dey routinely reported to the data reporting services were its AWPs and WACs, not its contract prices. (Paul Decl., Ex. 18 at 99:12-100:5.) Dey disputes CA-Dey-SOF ¶ 19 as immaterial and irrelevant on the grounds that California never required or expected Dey to report any such prices to pricing compendia. Dey further disputes any implication that it should have provided its contract prices to pricing compendia, or that California had any expectation that it would do so as there is no evidence in the record to support such a conclusion..

Dey hereby incorporates its response to CA-Dey-SOF ¶ 11 and evidence cited therein.

Dey hereby incorporates its response to CA-Dey-SOF ¶ 7 and evidence cited therein.

20. Dey was aware of Medicaid and Medi-Cal reimbursement policies in general. (Paul Ex. 20 (4/18/03 Carrie-Jean Jackson Dep.), at 109:6-112:9, Exs. 231 and 880 (containing Medi-Cal's reimbursement rates for Dey's products).)

RESPONSE:

Dey disputes CA-Dey-SOF ¶ 20 because the testimony cited does not provide evidence of any general pattern or knowledge of Dey which was improper or related to pricing or reporting of prices and is therefore irrelevant. The testimony cited by Plaintiffs refers to a low-level administrative employee who, by the time she left in 1995, held a receptionist title. (Reid Opp. Decl., Ex. 15, at 11:16-22, 52:21-23). Ms. Jackson worked for Dey for only six years, from 1989 until 1995, leaving the company approximately one year into the relevant time period. (Reid Opp. Decl., Ex. 15, at 11:10-15, 52:13-15). Neither Ms. Jackson's actions nor her testimony can serve as a credible indication of Dey's general business practices. Indeed, Dey did not regularly track how its products were being reimbursed by various state Medicaid agencies nor did it set prices based on such. (Reid Opp. Decl., Ex. 2, at 185:7-186:1). Dey's 30(b)(6) witness, Pamela Marrs, explained as follows:

> I mean, the documents that I've seen from the company at this point don't show evidence that there was a monthly report or any regular report that was distributed to people that had this kind of information on it. I'm not saying that people weren't generally aware that that was the reimbursement formula in some way. I -- I haven't seen documents that would suggest it was tracked in a regimented and structured way.

(Reid Opp. Decl., Ex. 2, at 185:13-186:1).

21. At various times during the relevant time period, Dey collected information concerning the particular reimbursement methodologies of the state Medicaid programs. (Paul Ex. 19 (2/10/03 Robert Ellis Dep.), at 12-17; Paul Ex. 20 (4/18/03 Carrie-Jean Jackson Dep.), at 109:6-112:9, Exs. 231 and 880; Paul Ex. 21 (12/28/02 First Databank Medicaid Coverage Report), at DL 59035, DL 59049, DL 59060-64, DL 59067-69; Paul Ex. 22 (12/17/98 FDB fax), at DL-CA 0063.)

RESPONSE:

Dey disputes CA-Dey-SOF ¶ 21 because the testimony cited does not provide evidence of any general pattern or knowledge of Dey which was improper or related to pricing or

reporting of prices and is therefore irrelevant. Dey hereby incorporates its response to Dey-SOF-¶ 20 and evidence cited therein.

Dey further disputes CA-Dey-SOF ¶ 21 on the grounds that the evidence cited does not support Plaintiffs' assertion that Dey collected information concerning state Medicaid reimbursement methodologies "[a]t various times." In fact, the memoranda sent by Ms. Jackson on August 12, 1993 and February 2, 1994 regarding reimbursement practices of state Medicaid and Medicare programs were the only two reports of their kind. (Reid Opp. Decl., Ex. 2, at 186:6-187:8; Reid Opp. Decl., Ex. 6, at 313:12-314:2). Ms. Jackson explained that after her February 1994 report it was specifically decided that such information would not be prepared on any systematic basis. (Reid Opp. Decl., Ex. 15, at 24:6-22). Robert Mozak, Executive Vice President of Sales and Marketing for Dey, L.P., testified that Ms. Jackson's reports were the only two ever compiled. (Reid Opp. Decl., Ex. 6, at 313:2-314:2).

22. Dey was aware that Medi-Cal reimbursed providers for pharmaceutical products based on the reported AWPs of the products. (Paul Ex. 20 (4/18/03 Carrie-Jean Jackson Dep.), at Ex. 231.)

RESPONSE:

Dey disputes CA-Dey-SOF ¶ 22 because the evidence cited does not provide evidence of any general pattern or knowledge of Dey which was improper or related to pricing or reporting of prices and is therefore irrelevant. The testimony cited by Plaintiffs simply confirms that as part of its business, Dey was aware of state Medicaid reimbursement in general terms. However, Dey did not track how its products were being reimbursed by various state Medicaid agencies, nor did it set prices based on such. (Reid Opp. Decl., Ex. 2, at 185:7-186:1). Dey's 30(b)(6) witness, Pamela Marrs, explained as follows:

> I mean, the documents that I've seen from the company at this point don't show evidence that there was a monthly report or any regular report that was distributed to people that had this kind of

> information on it. I'm not saying that people weren't generally aware that that was the reimbursement formula in some way. I -- I haven't seen documents that would suggest it was tracked in a regimented and structured way.

(Reid Opp. Decl., Ex. 2, at 185:13-186:1.)

23. Plaintiffs' expert, Dr. Leitzinger, used data provided by Dey to estimate the average prices paid by pharmaceutical wholesalers' customers [i.e., providers] for each of the 28 relevant Dey NDCs. Dr. Leitzinger did that by calculating the prices that wholesalers paid to Dey for each NDC and then applying a wholesaler markup to those prices to estimate the total amount that customers paid to wholesalers for each NDC. Paul Ex. 23 (Leitzinger Decl.), at ¶ 4. His methodology is explained more fully at paragraphs 12-20 of his Report, which is attached as Ex. A to his Declaration. The wholesaler markup that Dr. Leitzinger used was based on data contained in the "Industry Profile and Healthcare Factbook," published by the Healthcare Distribution Management Association. That markup ranged over time between 3.7 percent and 5.4 percent. (Paul Ex. 23 (Leitzinger Decl.), Ex. A at ¶ 20, n.20.)

RESPONSE:

For the purposes of this motion, Dey does not dispute that Dr. Leitzinger's report contains what Dr. Leitzinger purports to be average prices for the Subject Drugs, but Dey disputes that California had an expectation that Dey would calculate the AWPs for its Subject Drugs in the manner described in CA-Dey-SOF ¶ 23, that there is any basis to contend that Dey should have calculated its AWPs in the manner described in CA-Dey-SOF ¶ 23 or should have reported the figures listed in Dr. Leitzinger's report as its AWPs, or that Dr. Leitzinger's calculations are otherwise probative evidence of any of the elements of California's claims against Dey. (*See* Reid Opp. Decl., Ex. 16, at ¶¶ 186-87.)

Moreover, Plaintiffs' citation to Paragraph 20 and note 20 of Dr. Leitzinger's report is unavailing as they do not support the statements in CA-Dey-SOF ¶ 23.

24. Ex. 4 to Dr. Leitzinger's Report shows in column (6) the "spread" (the difference between the average net quarterly prices that he calculated and the reported AWP) for each of the 28 relevant Dey NDCs on a quarter-by-quarter basis from the first quarter of 1994 through the fourth quarter of 2004. (Paul Ex. 23 (Leitzinger Decl.), at ¶ 5.)

RESPONSE:

For the purposes of this motion, Dey does not dispute that Dr. Leitzinger's report contains what Dr. Leitzinger purports to be the difference between AWP and average prices for the Subject Drugs, but Dey disputes that Dr. Leitzinger's calculations of these figures are probative evidence of any of the elements of California's claims against Dey, or are probative evidence of the measure of the purported injury, if any, suffered by California.

25. For over 94 percent of the Dey NDC/quarter combinations for which he had complete data, the AWP reported by Dey exceeded the average net quarterly prices paid by wholesalers' customers by at least 100 percent. For 62 percent of those NDC/quarter combinations, the spread exceeded 300 percent, with some greater than 800 percent. (Paul Ex. 23 (Leitzinger Decl.), at ¶ 6.)

RESPONSE:

For the purposes of this motion, Dey does not dispute that Dr. Leitzinger's report contains what Dr. Leitzinger purports to be the difference between AWP and average prices for the Subject Drugs, but Dey disputes that Dr. Leitzinger's calculations of these "spreads" are probative evidence of any of the elements of California's claims against Dey, or are probative evidence of the measure of the purported injury, if any, suffered by California. (*See* Reid Opp. Decl., Ex. 16, at ¶¶ 36-37.)

26. For purposes of calculating the overpayments made by the State for the 28 relevant Dey NDCs, Dr. Leitzinger excluded claims for which the actual reimbursement did not exceed the average net price paid by wholesalers to Dey by at least 25 percent. For each remaining claim, he calculated the difference between the actual ingredient cost reimbursed by the State and an amount 25 percent above the average net price paid by wholesalers to Dey. That difference was the overpayment he found. (Paul Ex. 23 (Leitzinger Decl.), at ¶ 7.)

RESPONSE:

For the purposes of this motion, Dey does not dispute that Dr. Leitzinger's report contains what Dr. Leitzinger purports to be the difference between AWP and average prices for the Subject Drugs, but Dey disputes that there is any basis to conclude that California only ever

intended to reimburse providers at 25 percent above what wholesalers paid Dey to acquire drugs, or that Dr. Leitzinger's calculations are otherwise probative evidence of any of the elements of California's claims against Dey, or are probative evidence of the measure of the purported injury, if any, suffered by California. Dey further disputes that the existence of a difference between Medi-Cal's reimbursement payment for a drug and a providers' actual cost for a drug constitutes an "overpayment" because California deliberately adopted a reimbursement methodology that it knew would pay providers more than their actual acquisition costs for drugs to achieve its own policy goals. (*See* Reid Opp. Decl., Ex. 16, at ¶¶ 189-192; Joint SOF at ¶¶ 24-26, 33, 35-40, 52-53, 55, 67.)

27. All of the information used by Dr. Leitzinger in computing actual average wholesale prices for the Subject Drugs was contained in Dey's business records.

RESPONSE:

For the purposes of this motion, Dey does not dispute that Dr. Leitzinger's report contains what Dr. Leitzinger purports to be average prices for the Subject Drugs, but Dey states that Dr. Leitzinger's expert report, and the supporting material thereto, is the best evidence of Dr. Leitzinger's basis for his calculations. Dey disputes that the figures in Dr. Leitzinger's expert report are the "actual average wholesale prices" for the Subject Drugs or are otherwise probative evidence of the prices that Dey should have reported to the pricing compendia. California has never defined "Average Wholesale Price" as anything other than a price listed in a pricing compendia and there is no evidence that California ever understood or intended that AWPs should be actual averages of prices paid by wholesalers to acquire drugs, including the Subject Drugs. Dey further disputes that the "actual average wholesale prices" calculated by Dr. Leitzinger reflect prices that Dey could have calculated and reported on a regular basis that would be representative of prices paid on a forward-looking basis for Dey's drugs. Dey further

disputes that prices calculated using Dey's business records would accurately reflect prices actually paid by providers for the Subject Drugs. (*See* Reid Opp. Decl., Ex. 16, at ¶¶ 198-99.) Dey further disputes that Dr. Leitzinger's calculations are otherwise probative evidence of any of the elements of California's claims against Dey, or are probative evidence of the measure of any purported injury suffered by California, if any.

28. Dey directly negotiated prices for its products with contract customers, even when a product was shipped through a wholesaler. For those customers, Dey knew at least the approximate the [sic] price that the customers actually paid for the products. (Paul Ex. 24 (*United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey Inc., et al.*, Civil Action No. 05-11084- PBS Concise Statement of Undisputed Material Facts In Support of Dey, Inc., Dey, L.P., And Dey L.P., Inc.'s Motion For Partial Summary Judgment), at ¶¶ 52-53.)

RESPONSE:

Dey disputes CA-Dey-SOF ¶ 28 because Dey's Concise Statement of Undisputed Material Facts In Support of Dey, Inc., Dey, L.P., And Dey L.P., Inc.'s Motion For Partial Summary Judgment, *United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey Inc.*, Civil Action No. 05-11084- PBS, Docket No. 6190 ("Dey-US-SOF") does not support Plaintiffs' conclusion that "Dey knew at least the approximate [ ] price that the customers actually paid for the products." To the contrary, Dey-US-SOF ¶ 52 provides:

> In an indirect sale with a contract, Dey negotiates a contract price with an indirect customer *that will ultimately purchase Dey's product from a wholesaler*."

(emphasis added). Dey-US-SOF ¶ 53 states:

> The contract price sets forth the price between Dey and the indirect customer, *not the price between the indirect customer and the wholesaler*."

(emphasis added). The term "indirect sales" can encompass sales from the wholesaler to the wholesaler's customer (*e.g.*, pharmacy) where there is no contract between that customer and Dey. In those transactions, the wholesaler may have no contract with the customer, in which

case it would be an off contract transaction, or may have a separate contract with its customer not involving Dey. (Reid Opp. Decl., Ex. 17, at 171:10-18; Reid Opp. Decl., Ex. 18, at 182:11-21).

Dey does not know the terms of the contracts between wholesalers and their customers or the net prices paid by wholesaler customers to wholesalers. (Reid Opp. Decl., Ex. 19, at 104:10-12; Reid Opp. Decl., Ex. 2, at 78:12-79:10). As Dey's corporate designee, Ms. Marrs, testified:

> [W]e don't have visibility as to what price the wholesaler sells our product to what you're referring to as indirect sales or our contract customers.
>
> What we know is that we get a chargeback from the wholesaler, but it's my understanding that the wholesaler then takes that contract price – let's say we have a contract with a hospital at $10.
>
> We get a chargeback for the difference between the contract price and the price on the invoice that the wholesaler paid. So that's what we know.
>
> What we don't know is when the wholesaler then sells that product out to the hospital what kind of mark-up they add, because, obviously, they have to add some type of mark-up or they wouldn't stay in business. We don't have visibility as to what they ultimately sell it to the customer for.

(Reid Opp. Decl., Ex. 2, at 78:13-79:10).

REDACTED

For those transactions where Dey does have a contract with the wholesaler's customer, Dey does not know the final price to the customer. (Reid Opp. Decl., Ex. 2, at 78:12-79:10). While the contract price negotiated with Dey may be the base price, wholesalers are free to mark up or mark down for the service it provides in distributing the drug to the customer. (Reid Opp. Decl., Ex. 22, at 93:16-95:15, 169:1-170:1; Reid Opp. Decl., Ex. 23, at 156:15-157:2). Wholesalers may also give the customer discounts and rebates, which are not disclosed to Dey. (Reid Opp. Decl., Ex. 21, at 427:19-428:4, 432:12-21; Reid Opp. Decl., Ex. 20, at 767:17-768:14).

29. The information Dey received from First DataBank regarding the setting of generic AWPs was that in order to receive generic listing by FDB the generic AWP had to be priced *at least* 10% below the corresponding brand AWP, but there was no information that the generic AWP should be set at that level when its average wholesale price was lower. (Paul Ex. 24 (*United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey Inc., et al.*, Civil Action No. 05-11084-PBS, Concise Statement of Undisputed Material Facts In Support of Dey, Inc., Dey, L.P., And Dey L.P., Inc.'s Motion For Partial Summary Judgment), at ¶ 68.)

RESPONSE:

Dey does not dispute that Dey-US-SOF ¶ 68 states in full that "Ed Edelstein of First DataBank informed Dey that a generic AWP must be at least 10% lower than the corresponding brand AWP in order to be listed as such by First DataBank." Dey disputes CA-Dey-SOF ¶ 29 on the grounds that the evidence cited in no way supports Plaintiffs' conclusion that "there was no information that the generic AWP should be set at that level when its average wholesale price was lower." On the contrary, doing so was consistent with industry practice. (*See* Reid Opp. Decl., Ex. 4, at 460:2-462:10; Reid Opp. Decl., Ex. 8, at 21:4-18; Paul Decl., Ex. 4, at 731:12-24; Paul Decl., Ex. 3, No. 11 at 13-14.)

30. Rather than setting and reporting AWPs that reflected prices generally and currently paid by providers for its drugs, Dey reported AWPs for generics at approximately 10% off the brand AWP and generally left that price unchanged. (Paul Ex. 24 (*United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Dey Inc., et al.*, Civil Action No. 05-11084-PBS Concise Statement of Undisputed Material Facts In Support of Dey, Inc., Dey, L.P., And Dey L.P., Inc.'s Motion For Partial Summary Judgment), at ¶¶ 66, 70.)

RESPONSE:

Dey disputes CA-Dey-SOF ¶ 30. Dey hereby incorporates its response to CA-Dey-SOF ¶ 29.

Dated: December 21, 2009

KELLEY DRYE & WARREN LLP

/s/ Sarah L. Reid
Paul F. Doyle
William A. Escobar (admitted *pro hac vice)*
Sarah L. Reid (admitted *pro hac vice*)
Neil Merkl (admitted *pro hac vice*)
Christopher C. Palermo (admitted *pro hac vice*)
Philip D. Robben (admitted *pro hac vice*)
101 Park Avenue
New York, NY 10178
Telephone: (212) 808-7800
Facsimile: (212) 808-7897

Counsel for Defendants Dey, Inc. and Dey, L.P.

CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on December 21, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

/s/ Sarah L. Reid
Sarah L. Reid